

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO:) Judge Patti B. Saris
)
The City of New York v. Abbott Labs., et al.)
(S.D.N.Y. No. 04-CV-06054))
)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-05126))
)
and other cases listed on the following page)

**SEPARATE MEMORANDUM OF MERCK & CO., INC.
IN SUPPORT OF ITS MOTION TO DISMISS**

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March 3, 2006

THIS DOCUMENT RELATES TO:)	<i>County of Herkimer v. Abbott Labs, et al.</i>)
)	(N.D.N.Y. No. 05-CV-00415))
<i>The City of New York v. Abbott Labs., et al.</i>)	<i>County of Oneida v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 04-CV-06054))	(N.D.N.Y. No. 05-CV-00489))
<i>County of Suffolk v. Abbott Labs., et al.</i>)	<i>County of Fulton v. Abbott Labs, et al.</i>)
(E.D.N.Y. No. 03-CV-229))	(N.D.N.Y. No. 05-CV-00519))
<i>County of Westchester v. Abbott Labs., et al.</i>)	<i>County of St. Lawrence v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 03-CV-6178))	(N.D.N.Y. No. 05-CV-00479))
<i>County of Rockland v. Abbott Labs., et al.</i>)	<i>County of Jefferson v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 03-CV-7055))	(N.D.N.Y. No. 05-CV-00715))
<i>County of Putnam v. Abbott Labs, et al.</i>)	<i>County of Lewis v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 05-CV-04740))	(N.D.N.Y. No. 05-CV-00839))
<i>County of Dutchess v. Abbott Labs, et al.</i>)	<i>County of Chautauqua v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 05-CV-06458))	(W.D.N.Y. No. 05-CV-06204))
<i>County of Washington v. Abbott Labs, et al.</i>)	<i>County of Allegany v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00408))	(W.D.N.Y. No. 05-CV-06231))
<i>County of Rensselaer v. Abbott Labs, et al.</i>)	<i>County of Cattaraugus v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00422))	(W.D.N.Y. No. 05-CV-06242))
<i>County of Albany v. Abbott Labs, et al.</i>)	<i>County of Genesee v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00425))	(W.D.N.Y. No. 05-CV-06206))
<i>County of Warren v. Abbott Labs, et al.</i>)	<i>County of Wayne v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00468))	(W.D.N.Y. No. 05-CV-06138))
<i>County of Greene v. Abbott Labs, et al.</i>)	<i>County of Monroe v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00474))	(W.D.N.Y. No. 05-CV-06148))
<i>County of Saratoga v. Abbott Labs, et al.</i>)	<i>County of Yates v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00478))	(W.D.N.Y. No. 05-CV-06172))
<i>County of Columbia v. Abbott Labs, et al.</i>)	<i>County of Niagara v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00867))	(W.D.N.Y. No. 05-CV-06296))
<i>Essex County v. Abbott Labs, et al.</i>)	<i>County of Seneca v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00878))	(W.D.N.Y. No. 05-CV-06370))
<i>County of Chenango v. Abbott Labs, et al.</i>)	<i>County of Orleans v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00354))	(W.D.N.Y. No. 05-CV-06371))
<i>County of Broome v. Abbott Labs, et al.</i>)	<i>County of Ontario v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00456))	(W.D.N.Y. No. 05-CV-06373))
<i>County of Onondaga v. Abbott Labs, et al.</i>)	<i>County of Schuyler v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00088))	(W.D.N.Y. No. 05-CV-06387))
<i>County of Tompkins v. Abbott Labs, et al.</i>)	<i>County of Chemung v. Abbott Lab, et al.</i>)
(N.D.N.Y. No. 05-CV-00397))	(W.D.N.Y. No. 05-CV-06744))
<i>County of Cayuga v. Abbott Labs, et al.</i>))
(N.D.N.Y. No. 05-CV-00423)))
<i>County of Madison v. Abbott Labs, et al.</i>)	and)
(N.D.N.Y. No. 05-CV-00714))	<i>County of Nassau v. Abbott Labs, et al.</i>)
<i>County of Cortland v. Abbott Labs, et al.</i>)	(E.D.N.Y. No. 04-CV-05126))
(N.D.N.Y. No. 05-CV-00881)))

**SEPARATE MEMORANDUM OF MERCK & CO., INC.
IN SUPPORT OF ITS MOTION TO DISMISS**

Defendant Merck & Co., Inc. (“Merck”) submits this separate memorandum in support of its motion to dismiss both the Consolidated Complaint of New York City and Plaintiff New York Counties Other Than Nassau (the “Consolidated Complaint”) and the Second Amended Complaint of Nassau County (the “Nassau Complaint”) (together, the “Complaints”). Merck also joins in Defendants’ Joint Memorandum of Law in Support of Motion to Dismiss the same Complaints (the “Joint Memorandum”).

Discussion

In its three *Suffolk County* decisions, the Court dismissed all claims of Suffolk County against Merck (and the other “Suffolk 13” defendants) in incremental stages.¹ The Complaints now before the Court seek to revive those claims, but fail to correct the deficiencies that caused the Court to dismiss Suffolk County’s claims. The Joint Memorandum explains why the claims now asserted in the Complaints should be dismissed as to all defendants as a matter of law. Merck files this separate memorandum to focus on the failure of the Complaints to allege any wrongdoing by Merck.

1. Rule 9(b) cannot be satisfied by calling a price “fraudulent” or “substantially less” than AWP.

The showpiece of the Consolidated Complaint is Exhibit B, which lists pages of price figures under the heading “Fraudulent AWP,” as though calling a price fraudulent makes it so. In Merck’s case, Exhibit B purports to compare an alleged “Market Price” of unidentified origin

¹ *County of Suffolk v. Abbott Labs, et al.*, 339 F. Supp. 2d 165 (D. Mass. Sep. 30, 2004) (*Suffolk I*); *County of Suffolk v. Abbott Labs, et al.*, 2004 WL 2387125 (D. Mass. Oct. 26, 2004) (*Suffolk II*); Memorandum and Order dated April 8, 2005 (*Suffolk III*).

to the published AWP of a few formulations of two products, Mefoxin® and Pepcid®.² Market Prices are described as “available wholesale prices.” Consol. Compl. ¶ 124. The Consolidated Complaint alleges as to Mefoxin® and Pepcid® only that “Each available price is substantially less than the false and inflated Merck AWP which served as the basis for the County Medicaid Program’s reimbursements.” Consol. Compl. ¶ 598. The Nassau Complaint makes a similar comparison as to the same two Merck products in its Exhibit A, asserting that the “generally available market prices” alleged are “significantly less than the false and inflated AWP and WACs which served as the basis for the Nassau County Medicaid Program’s reimbursements.”³ Nassau Compl. ¶ 498.

The Complaints do not say why these alleged differences constitute *fraud*. Indeed, as this Court has recognized, differences between AWP and actual pricing are common knowledge: “Typically, the AWP for a brand-name, self-administered drug is 20% or 25% above WAC.” *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 68 (Aug. 16, 2005). See Consol. Compl. ¶¶ 6-7 (20-25% markup to WAC is “generally accepted”); Nassau Compl. ¶ 5 (“It is well-recognized that WAC should be 20 to 25% lower than AWP”). Simply alleging that undefined “market prices” are available from unspecified sources and are “substantially” or “significantly” less than AWP does not constitute an allegation of the “time,

² Neither Merck nor Mefoxin® nor Pepcid® is even mentioned in Exhibit F to the Consolidated Complaint, captioned “Spreads between Published AWP and WACs.”

³ No formulation of Mefoxin® is listed in Nassau’s Exhibit B, which lists “Nassau County Drug Expenditures,” and the only formulation of Pepcid® listed in Exhibit B does not appear on the list of alleged spreads in Nassau’s Exhibit A. Thus, Nassau County does not allege that it actually paid for any of the Merck drugs for which it alleges a difference between Market Price and AWP.

place, and content of the alleged false or fraudulent representations” sufficient to satisfy Rule 9(b). *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004); *Massachusetts v. Mylan Laboratories*, No. 03-11865-PBS, Mem. at 2 (D. Mass. Apr. 5, 2005).

Each of the Complaints thus fails as to Merck “to present more particular information about its allegation that the published AWP for each drug was fraudulent.” *Suffolk III* at 1. Both Complaints should accordingly be dismissed.

2. Allegations of unadjudicated and irrelevant investigations cannot support an inference of fraud.

The Complaints attempt to satisfy this Court’s requirement that an AWP complaint contain factual allegations “from which an inference of fraud can reasonably be made,” *Suffolk II* at *4, by alleging that Merck is being or has been investigated by someone for something. *E.g.* Consol. Compl. ¶¶ 600-607; Nassau Compl. ¶¶ 502-508. These efforts fail, first, because allegations of investigations that have not resulted in an adjudication are inadequate as a matter of law, and, second, because the investigations alleged have nothing to do with the AWP-based causes of action that the Complaints attempt to plead.

A federal court in New York, in an opinion handed down after the last of this Court’s *Suffolk* decisions, marshaled authority for the proposition that:

“even if those allegations were relevant, courts hold that references in pleadings to administrative investigations that *do not result in adjudication* of underlying issues are immaterial and can properly be stricken under Rule 12(f).”

Gotlin v. Lederman, 367 F. Supp. 2d 349, 363 (E.D.N.Y. 2005) (emphasis added). The *Gotlin* court cited, *inter alia*: *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976) (granting motion to strike allegations about consent judgment with the SEC and the complaint resulting in that judgment that were not the result of actual adjudication of any issues); and *In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig.*, 218 F.R.D. 76, 79 (S.D.N.Y. 2003)

(granting motion to strike portions of complaint referring to SEC investigations in other litigations involving defendant). The Complaints do not even attempt to allege that any of the investigations involving Merck has resulted in an adjudication. The allegations relating to those investigations thus cannot support an inference of fraud.

The investigations alleged are also manifestly irrelevant to the AWP claims the Complaints attempt to assert. Most are alleged to involve whether various discounts were or should have been taken into account in calculating Best Price. Consol. Compl. ¶¶ 601-607; Nassau Compl. ¶¶ 502-508. But neither of the Complaints adequately pleads a Best Price claim. *See* Joint Memorandum Point IV.B. The other allegations involve incomplete Congressional inquiries and unadjudicated *qui tam* complaints related to the alleged exclusion by Merck, in making price calculations, of “nominal prices” charged to certain hospitals.⁴ The Consolidated Complaint (¶ 154) describes the “nominal price exception to Best Price reporting” as one:

“created by Congress as a public policy exception to encourage drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good, without the manufacturer having to pay increased rebates because of those sales. The exception allows drug companies to exclude from their Best Price calculations drugs with prices less than 10% of AMP.”

On the face of the Consolidated Complaint, therefore, the nominal price exception also relates to the Best Price calculation.

While the Consolidated Complaint alleges that “these deeply discounted [nominal] prices have not been included in the AWPs or other wholesale information that Merck reports or causes to be reported,” Consol. Compl. ¶ 606, it gives no reason why they should have been. The so-called “spread” upon which the Complaints claim to be predicated relates to the difference

⁴ The proper purpose of a Congressional inquiry, of course, is to determine whether laws need to be enacted or amended, not whether a law has been violated.

between the actual price paid by a pharmacy for a product supplied to a Medicaid patient and the AWP upon which the State of New York has chosen to base its Medicaid reimbursement formula. Whether that same product was sold to another buyer for a different price can be relevant only to establishing the Best Price used to calculate the Medicaid rebate paid by the manufacturer to the State, not to the spread. Unadjudicated investigations into discounts and nominal prices simply have nothing to do with this case and cannot support any inference of fraud.

Conclusion

For the reasons stated above and in the Joint Memorandum, the Consolidated Complaint and the Nassau Complaint should be dismissed as to Merck.

Dated: March 3, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on March 3, 2006, I caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Robert B. Funkhouser
Robert B. Funkhouser